



NAME: COMMANDER (CDR) ALICIA M.  
MOZZACHIO

JOB TITLE: CONSUMER SAFETY OFFICER

AGENCY: FOOD AND DRUG ADMINISTRATION  
(FDA)

**EDUCATION/DEGREES/CERTIFICATES/INSTITUTIONS:**

CDR Alicia Mozzachio graduated in 1993 from Temple University in Philadelphia, PA with a B.S. in Pharmacy. She is planning to obtain a Masters in Public Health at some point in the future.

**CURRENT JOB DESCRIPTION:**

CDR Mozzachio conducts inspections of international pharmaceutical manufacturing facilities to evaluate their compliance with current Good Manufacturing Practices (cGMPs) and their ability to meet Abbreviated New Drug Application (ANDA) requirements. As a compliance officer, she reviews inspection reports from other FDA investigators to determine if regulatory or administrative action is warranted. When warranted, the compliance officer initiates regulatory or administrative action ensuring that all deficiencies are corrected. She also answers cGMP inquiries and gives presentations to FDA staff and the pharmaceutical industry on cGMPs and conducting pharmaceutical inspections, drafts and reviews cGMP guidance documents, and helps train FDA field investigators.

**QUALIFYING SKILLS FOR CURRENT POSITION AND PREVIOUS USPHS ASSIGNMENTS:**

After graduation, CDR Mozzachio worked for ten years as an Investigator with FDA's Office of Regulatory Affairs (ORA). In this position, she conducted inspections of pharmaceutical manufacturing sites. Conducting these inspections allowed her to increase her knowledge of regulatory practices and to develop skills for conducting inspections in the international arena. In addition, her position allowed her to travel extensively visiting approximately 20 different countries in just 10 years. CDR Mozzachio believes that her pharmacy training and education helped her immensely in her career with FDA, specifically with critical thinking and the ability to evaluate whether firms' practices are scientifically sound. In addition to her previous experiences, FDA provides an extensive training program for all new investigators to hone their investigation skills and techniques as well as broaden their knowledge of relevant FDA regulations.

**REASONS FOR CHOOSING THE USPHS AS A CAREER:**

After successfully completing two Commissioned Officer Student Training and Extern Program (COSTEP) assignments in Cherokee, NC and Rockville, MD, CDR Mozzachio realized that the USPHS Commissioned Corps would allow her to serve the public in a

non-traditional role as a pharmacist. She chose this path with the mission of keeping the public safe and ultimately improving Americans health-related quality of life.

#### **MOST REWARDING USPHS PROFESSIONAL EXPERIENCE:**

In December 2004, CDR Mozzachio received a call for volunteers with regulatory experience to deploy to Baghdad, Iraq. She felt honored and privileged to represent the pharmacy category of the USPHS knowing that many qualified and capable officers had also volunteered for this deployment. After a week of military training in El Paso, Texas, CDR Mozzachio deployed to Iraq in March 2004. She was assigned to the Ministry of Health (MOH) Team within the Coalition Provisional Authority (CPA) under the direction of Mr. James Haveman, Senior Advisor. Her primary role would be to assist the Iraqi Ministry of Health registration committee with revising their regulations related to imported drug products in an attempt to streamline the process and make it more transparent to the pharmaceutical companies wishing to sell their products in Iraq. Her team formed a committee of specialists to define all documentation required for submission by pharmaceutical manufacturers. As military and civilian personnel assigned to the MOH began to transition out of Baghdad, CDR Mozzachio inherited additional responsibilities relating to critical drug shortage issues. Two emergency drug buys totaling \$44 million were initiated to improve the drug shortage problem. CDR Mozzachio was responsible for ensuring the appropriate delivery of these drugs to MOH warehouses throughout Iraq. CDR Mozzachio completed her deployment in June 2004 as Iraq's CPA was transitioning power back to the Iraqis.

#### **OTHER PROFESSIONAL INTERESTS/ACTIVITIES:**

- CDR Mozzachio recently had an article published entitled "A World Away" which can be found in the Am J of Health-Syst Pharm (AJHP). 2005; 62:753-9.
- She participated in an HHS/DoD Symposium on Civil-Military Medicine and is a working group member for revising a doctrine related to interagency disaster relief missions.
- She is a guest lecturer on inspectional techniques at FDA's Basic Drug School and during meetings with industry.

*By LT Paras Patel*